

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., and ENDO	)	
PAR INNOVATION COMPANY, LLC,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
	)	
ZYDUS PHARMACEUTICALS (USA) INC.	)	
and ZYDUS LIFESCIENCES LTD.	)	
	)	
Defendant.	)	
	)	

**DECLARATION OF ROBERT D. RHOAD IN SUPPORT OF  
PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER,  
PRELIMINARY INJUNCTION, AND EXPEDITED DISCOVERY**

I, Robert D. Rhoad, hereby declare as follows:

1. I am an attorney at Dechert LLP, counsel of record for Plaintiffs Par Pharmaceutical, Inc. and Endo Par Innovation Company, LLC (collectively "Par") in the above-captioned litigation. I make this declaration in support of Par's Motion for Temporary Restraining Order, Preliminary Injunction, and Expedited Discovery.

2. Attached hereto as Exhibit 1 is a true and correct copy of United States Patent No. 11,717,524.

3. Attached hereto as Exhibit 2 is a true and correct copy of "Control of Nitrosamine Impurities in Human Drugs", Guidance for Industry, U.S. Food and Drug Administration Center for Drug Evaluation and Research (Feb. 2021, Rev. 1).

4. Attached hereto as Exhibit 3 is a true and correct copy of a printout of "Laboratory Analysis of Varenicline Products," U.S. Food and Drug Administration, available at

<https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-varenicline-products>  
(Aug. 23, 2021).

5. Attached hereto as Exhibit 4 is a true and correct copy of a letter sent by me to Zydus Pharmaceuticals and Zydus Pharmaceuticals USA Inc., dated May 17, 2023.

6. Attached hereto as Exhibit 5 is a true and correct copy of a letter sent by me to Zydus Pharmaceuticals and Zydus Pharmaceuticals USA Inc., dated June 9, 2023.

7. Attached hereto as Exhibit 6 is a true and correct copy of a press release titled “Zydus receives final approval from the USFDA for Varenicline Tablets,” dated June 13, 2023, available at <https://www.zyduslife.com/investor/admin/uploads/21/83/Zydus-receives-final-approval-from-the-USFDA-for-Varenicline-Tablets.pdf>.

8. Attached hereto as Exhibit 7 is a true and correct copy of the approved prescribing information and labeling for Zydus Lifesciences’ varenicline tartrate tablets.

9. Attached hereto as Exhibit 8 is a true and correct copy of an email send to me from James Peterka of the Locke Lord firm, dated June 21, 2023.

10. Attached hereto as Exhibit 9 is a true and correct copy of an email I sent to Mr. Peterka on June 21, 2023, along with the accompanying letter and non-disclosure agreement attached thereto.

11. Attached hereto as Exhibit 10 is a true and correct copy of a printout of “FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix),” U.S. Food and Drug Administration, available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix> (May 5, 2022).

12. Attached hereto as Exhibit 11 is a true and correct copy of Plaintiffs’ First Set of Requests for Production of Documents.

13. Attached hereto as Exhibit 12 is a true and correct copy of a printout from the U. S. Food and Drug Administrations's Drugs@FDA website, available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=216723>.

14. Attached hereto as Exhibit 13 is a true and correct copy of a document titled "Quantification of N-Nitrosovarenicline in Zydus Varenicline Tartrate Tablets."

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 8, 2023

/s/ Robert D. Rhoad  
Robert D. Rhoad